REPORT TITLE

Request for waiver of GLP Acute Inhalation and Dermal Sensitization Studies
MCC 3-Way Fungicide and Submittal of 2 non-GLP Studies

DATA REQUIREMENT

OCSPP 870.1300, 870.2600

AUTHOR

D. O'Shaughnessy Ph.D., DABT

COMPLETION DATE

Oct. 8, 2013

FACILITY

N/A

SPONSOR

Agromarketing Company, Inc.
Toronto ON, CANADA

SUBMITTER

D. O'Shaughnessy Consulting, Inc.,
427 Hide Away Circle, Cub Run, KY 42729

MRID 49229506

STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this report on the basis of its falling within the scope of FIFRA § 10(d)(1)(A), (B) or (C).

Company: Agromarketing Company

Company Agent: D. O'Shaughnessy, Ph.D. DABT, DABFM

Title: President, D.O.C. Inc., Agent for Agromarketing Company.

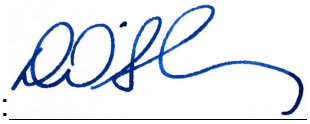
Signature:  Date: Oct. 8, 2013

STATEMENT OF GOOD LABORATORY PRACTICE COMPLIANCE

The descriptive information in this report is not subject to the requirements of 40 CFR Part 160.

Author:

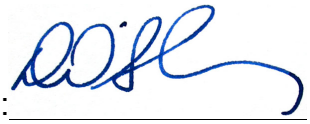
D. O'Shaughnessy
D.O.C., Inc.

Signature: 

Date: Oct. 8, 2013

Sponsor/Submitter:

D. O'Shaughnessy
President
D.O.C., Inc.,
Agent for Agromarketing Company

Signature: 

Date: Oct. 8, 2013

Product: MCC 3-Way Fungicide, 87845-X

Composition: 29% copper oxychloride, 12% mancozeb, 4% cymoxanil
Refer to the CSF supplied with this application for detailed formulation information.

1. REQUEST FOR WAIVER OF GLP ACUTE INHALATION

Agromarketing Company hereby requests waiver of requirement for a GLP inhalation study for the subject product on the basis of the following:

1. Non- GLP studies have been conducted by the manufacturer, and a non-GLP study is attached (Appendix 1). Although not conducted according to GLP (40 CFR 160), this study was conducted in compliance with the requirements of the Bulgarian State Standards (BSS 15380-81) and for Good Laboratory Practice (Guidelines for Good Laboratory Practice (Drug Research Institute, Ministry of Health, 1997), as well as of the European Union countries (OECD, Environmental Monograph No 45, OECD Guidelines for Testing of Chemicals, No. 401 Directive 92/69/EEC, Method B1).

2. Similar combinations have been recently tested according to GLP and have been submitted in support of related products (cymoxanil + mancozeb mixture, MRID 49214806, and copper + cymoxanil, MRID 49214706). In both cases, a Category 3 or Category 4 level of toxicity is indicated. Agromarketing has permission to cite these data.

3. The product is composed of non-volatile components, and is not intended for use in high pressure spraying apparatus which could produce particles of respirable size.

4. None of the three individual components are expected to be unduly toxic by inhalation.

In view of the above, we believe that a repeat of this study would represent undue use of laboratory animals which would not add to the determination of label precautionary language, and that the non-GLP data should suffice.

2. REQUEST FOR WAIVER OF GLP SENSITIZATION STUDY

Agromarketing Company hereby requests waiver of requirement for a GLP inhalation study for the subject product on the basis of the following:

1. Non- GLP studies have been conducted by the manufacturer, and a non-GLP study is attached (Appendix 1). Although not conducted according to GLP (40 CFR 160), this study was conducted in compliance with the requirements of the Bulgarian State Standards (BSS 15380-81) and for Good Laboratory Practice (Guidelines for Good Laboratory Practice (Drug Research Institute, Ministry of Health, 1997), as well as of the European Union countries (OECD, Environmental Monograph No 45, OECD Guidelines for Testing of Chemicals, No. 401 Directive 92/69/EEC, Method B1).

2. Similar combinations have been recently tested according to GLP and have been submitted in support of related products (cymoxanil + mancozeb mixture, MRID 49214809, and copper + cymoxanil, MRID 49214709). In both cases, the products are non-sensitizing. Agromarketing Company has permission to cite these data.

3. None of the individual components are expected to be sensitizers.

In view of the above, we believe that a repeat of this study would represent undue use of laboratory animals which would not add to the determination of label precautionary language, and that the non-GLP data should suffice.